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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/026,610	12/21/2001	Stephen Quirk	15829	9118
23556	7590	06/29/2004	EXAMINER	
KIMBERLY-CLARK WORLDWIDE, INC. 401 NORTH LAKE STREET NEENAH, WI 54956			SNAY, JEFFREY R	
			ART UNIT	PAPER NUMBER
			1743	

DATE MAILED: 06/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/026,610	QUIRK ET AL.	
	Examiner	Art Unit	
	Jeffrey R. Snay	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-34 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/7/02, 3/9/04</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Oberhardt ('133).

Oberhardt disclose an analytical device which comprises all of the presently recited features. Specifically, see Figures 3-4B of Oberhardt depicting an assay device comprising a test element (30) and a means for inducing a pressure differential (syringe) for driving sample fluid to and from the test element. The surface of test element (30) is optically analyzed after contact with the sample (e.g. column 6, lines 20-25).

Regarding the presently recited limitation that the test surface is a diffraction based surface, including binders printed thereon, see Oberhardt at column 9, first paragraph, teaching that specific binding partners are immobilized on the test surface for interaction with sample analyte. Such immobilization of binding partners is the only definition given by the instant specification for a "diffraction based" surface, and the anticipating structure of Oberhardt therefore implicitly anticipates any presently recited intended use.

Regarding the presently recited means for inducing a pressure differential as comprising either a positive or negative pressure inducement, see Oberhardt at Figures 4A and 4B disclosing both options.

Regarding the presently recited means for informing a user that a particular position has been reached, note Figure 3 of Oberhardt. The depicted syringe includes a syringe piston having a diameter greater than the distal end of the syringe chamber. As such, the abutment of the syringe piston at the end of its stroke would have provided an indication of its position.

Regarding the presently recited means for separating and means for diluting, see Oberhardt at column 9, lines 61-65, and column 16, lines 5-8, respectively, teaching these features.

Regarding the presently recited diffraction enhancing elements, see Oberhardt at column 9, first paragraph, teaching the presence of either magnetic or glass beads. Such beads would have inherently constituted diffraction enhancing elements.

Regarding the presently recited feature that the test element is removable, see Figure 3 of Oberhardt depicting the test element as connected to the syringe via a luer fitting. Such fitting would have rendered the element removable from the syringe. See also column 6, lines 2-25, disclosing operation of the device as including placing the test element in the testing device, which implies also that the test element can be subsequently removed.

Regarding the presently recited capillary, see Oberhardt at column 6, lines 45-53 disclosing a capillary providing capillary action as the motive force for transferring sample fluid across the test surface.

3. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure as background information related to applicant's field of endeavor.

Information Disclosure Statement

4. The information disclosure statement filed 03-07-02 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein, indicated by those references which have been lined through on the attached form 1449, has not been considered.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey R. Snay whose telephone number is (571) 272-1264. The examiner can normally be reached on Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1743

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jeffrey R. Snay
Primary Examiner
Art Unit 1743

jrs